REMARKS

At page 8 of the Office Action of 2 March 2004, the Examiner indicated that the features of improved transdermal flow rate should be placed in the claim to more clearly distinguish from the prior art. In order to expedite prosecution, applicants have amended claim 1 to recite not only the higher amounts of specific compound (i.e., 3-20 % (m/m) dissolved in the polyacrylate matrix) but the transdermal skin flow rate of $\geq$100 ng/cm2/h between 10 h and 42 h as determined in a Franz-flow cell. Support for the amendments to claims 1 and 4 can be found, for example, at page 3, line 26; at page 9 last paragraph, example 2 and 3, and figure 2.

The Rejection under 35 U.S.C. §103

The rejection of claims 1-26 under 35 U.S.C. §103 as being unpatentable over Schollkopf et al. (US 5,827,842), Li (WO 96/40087), Lipp (U.S. Patent No. 5,676,968) and Hansen et al. (US 5,120,546) is respectfully traversed.

Schollkopf et al. discloses a large class of new steroids, preferably for oral administration (see col.6 line13), including the compound recited in the claims. At col. 6, lines 29-31, Schollkopf suggests that it is possible to incorporate the broad class of disclosed substances into a transdermal system, although there is no guidance of which specific transdermal matrix to choose or any other guidance of available classes of transdermal systems. Applicant's transdermal system is based on a specific matrix (polyacrylate) and about 3-20 % of a specific compound that is both highly soluble and highly potent when dissolved in the polyacrylate matrix. One skilled in the art considering Schollkopf would derive no hint that these details should be chosen.

Li discloses acrylate adhesives which are crosslinked with aluminum acetylacetonate. Such crosslinked adhesives are not included within "polyacrylate adhesives"(see page 3, sixth paragraph of the specification). Additionally, Li only mentions two specific gestagens in claim 7, which are different from that of the claims, and there are no suggestions or guidance directing one skilled in the art to any other gestagens.

As previously noted, Lipp teaches away from use of the active ingredient of the invention (See col. 2, lines 48-59). Hansen uses cyclic polysaccharides to form an inclusion compound and merely discloses a large group of components which may be included within transdermal systems.

Gestagens are not freely interchangeable and thus, this combination of prior art does not lead to a selection of applicant's gestagen for use in polyacrylate systems.

This invention uses about 3-20% (m/m) of a specific high potency gestagen dissolved in a polyacrylate matrix and achieves transdermal skin flow rate of $\geq$100 ng/cm2/h between 10 h and 42 h as determined in a Franz-flow cell. Example 3 of applicant's specification directly compares the transdermal skin flow of gestodene (disclosed in examples 5 and 6 of Lipp) and hydroxytrienedione. As graphically depicted in figure 2, the skin flows for 1% matrix transdermal systems of hydroxytrienedione and gestodene are comparable. However, gestodene loading cannot increase above about 1% without resulting in a recrystalization phenomenon (page 14, line 17) and thus the skin flow of gestodene cannot exceed values achieved at 1%. Figure 2 further depicts examples of TDS systems loaded with from 3- 15 % of the agent recited in the claims. They very clearly show a much higher skin flow than the highest achievable levels for gestodene of the prior art.

Thus, in light of the above remarks, the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

Respectfully submitted,

Anthony J. Zelano
Registration No. 27,969
Attorney for Applicants

Jennifer Branigan
Registration No. 40,921
Agent for Applicants

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1
2200 Clarendon Blvd. Suite 1400
Arlington, Virginia 22201
Telephone: (703)812-5305
Facsimile: (703) 243-6410

Attorney Docket No.: SCH-1859

Date: **4 October 2004**
jjb:K:\Sch\1859\resp08-02-04.doc